DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/09 has been entered.

Claims 1, 4 have been amended. Claims 2, 3, 32, 36 have been canceled. Claims 1, 4, 5, 7-11, 28-31, 33-35 are pending.

All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office action mailed on 4/7/09 are withdrawn in view of the amendments and the following examiner's amendment.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Quang D. Nguyen on September 2, 2009.

The claims have been amended as follows:

1. (Currently amended) A method for producing therapeutic human T regulatory cells (Treg cells) ~~with enhanced suppressor activity~~, said method comprising:

selecting a sample of human $CD4^+$ T cells;

contacting said sample with an anti-CD25 antibody;

isolating cells that bind to said anti-CD25 antibody from said sample using a double column magnetic antibody cell sorting (MACS) purification procedure, to produce an isolated population of human CD4+$CD25^+$ Treg cells;

culture-expanding said population of human CD4+$CD25^+$ Treg cells comprising contacting said isolated population of human CD4+$CD25^+$ Treg cells with immobilized anti-CD3 antibody and immobilized anti-CD28 antibody, further culture-expanding said isolated population of human CD4+$CD25^+$ Treg cells in the presence of ~~a~~ an irradiated $CD4^+$ feeder cell or the irradiated $CD4^+$ feeder cell conditioned medium, thereby producing culture-expanded therapeutic human Treg cells ~~with enhanced suppressor activity~~, wherein said culture-expanded Treg cells are CD62L+/$CD27^+$ and are capable of inhibiting proliferation of CD4+CD25- responding T cells in a Mixed Lymphocyte Reaction (MLR) assay by at least 90%.

In claim 5, --subject-- was inserted after “human”.

11. (Currently amended) The method of claim 1, wherein the sample of human $CD4^+$ T cells is selected from the group consisting of whole or partially purified blood or hematopoietic cells, wherein said hematopoietic cells are selected from the group consisting of peripheral blood mononuclear cells, peripheral blood lymphocytes, spleen cells, tumor-infiltrating lymphocytes and lymph node cells, and bone marrow ~~and peripheral bone marrow~~ cells.

Claim 28 (Canceled).

Conclusion

Claims 1, 4, 5, 7-11, 29-31, 33-35 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on 571-272-0739. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
September 10, 2009